

**Application No.:** 10/550,297  
**Filing Date:** September 21, 2005

### **REMARKS**

Claims 21-35 stand rejected, and are presented for consideration and further examination in view of the following remarks.

#### **Withdrawal of Finality**

Applicants respectfully request that the finality of the Office Action mailed October 30, 2008 be withdrawn as agreed by the Examiner during the telephonic interview discussed in the Summary of Interview above.

#### **Rejections of Claims 21-28 and 31-35 under 35 U.S.C. § 102(e)**

The Examiner rejected Claims 21-23, 28, and 31-35 under 35 U.S.C. § 102(e) as being anticipated by U.S. Publication No. 2003/0023302 (Moe et al.). The Examiner has also rejected Claims 24-27, 29, and 30 under 35 U.S.C. § 103(a) as being unpatentable over Moe et al. in view of one of U.S. Patent No. 4,345,340 (Rosen), U.S. Patent No. 4,851,000 (Gupta), or U.S. Publication No. 2001/0039450 (Pavcnik). With respect to the anticipation rejection of independent Claim 21, Applicant respectfully submits that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *See* M.P.E.P. § 2131.

Referring to Figure 1 of Moe et al., the Examiner asserts that Moe et al. discloses “a biological prosthesis comprising an aortic valve obtained from an animal (11, paragraphs 0004-0005); a tubular wall (12), and a reinforcement device (16) comprising a rod (13) implanted in the tubular outer wall.” Applicant respectfully submits, however, that the Examiner has misunderstood the disclosure of the Moe et al. reference.

Paragraphs 0004-0005 referred to by the Examiner merely provide background information on possible materials used for forming conventional prosthetic heart valves. These paragraphs mention that prosthetic heart valves include mechanical valves, polymer valves, and “bioprosthetic valves using biological tissue.” (Paragraph 0004). The background section of the Moe et al. reference does not, however, mention bioprosthetic valves comprising a natural biological valve, such as the claimed “aortic valve obtained from an animal.” Instead, the

background section of the Moe et al. discloses that conventional bioprosthetic valves are composited from “porcine or bovine pericardium tissue.” (Paragraph 0005).

The focus of the Moe et al. reference is a sewing cuff assembly for a prosthetic valve. (Abstract). In discussing the sewing cuff assembly, Moe et al. describes a prosthetic heart valve comprising a “biocompatible polymer such as a silicone or polyurethane.” (Paragraph 0022). Reference numeral 11 of Moe et al., identified by the Examiner as corresponding to the claimed “aortic valve obtained from an animal,” is in fact part of a polymer valve, and not a natural tissue valve from an animal, as asserted by the Examiner. (Paragraph 0022). Thus, Applicant respectfully submits that Moe et al. fails to disclose a “biological prosthesis comprising an aortic valve obtained from an animal,” as recited in independent Claim 21.

Further, from the disclosure of the Moe et al. reference it is apparent that the tabs form a circumference which is smaller than an inner circumference of the valve body 12. In particular, paragraph [0024] of the Moe et al. reference recites that “the outer ring 22 preferably has an inner circumference slightly smaller than the valve body measured around the outer surface of the tabs 14.” Thus, the stent 16 of Moe et al. is an intraluminal device, and not an “*intraparietal* reinforcement device” as recited in Claim 21 (emphasis added).

As discussed above, the devices of Moe et al. do not contain biological tissue but rather employ a biocompatible polymer such as a silicone or polyurethane. Furthermore, the stents 16 (and tabs 13) of the Moe et al. reference are not implanted in the valve body 12 but rather are placed in a space between two layers of the polymer (see Fig. 1 A depicting tabs 13 positioned in a space between two layers of the polymeric valve body 12). Thus, Moe et al. does not disclose “a rod penetrating the thickness of the tubular outer wall of the aortic valve” as recited in the currently pending claims.

In view of the foregoing, Applicant respectfully submits that Moe et al. fails to disclose “an intraparietal reinforcement device comprising a rod implanted in [a] tubular outer wall of [an] aortic valve, the rod penetrating the thickness of the tubular outer wall of said aortic valve,” as recited in independent Claim 21.

Furthermore, as attested in the accompanying Declaration of Dr. Norman Jaffe, if the device of Moe et al. were modified to employ biological tissue rather than the biocompatible

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polymer taught by this reference, the resulting device would be expected to fail as a result of erosion of the leaflet tissue resulting from contact between the tissue and the stent structure.

The applied prior art of record does not cure these deficiencies in the Moe et al. reference. Accordingly, because Moe et al. does not disclose each and every element of Claim 21, Applicant respectfully submits that the rejection of independent Claim 21 has been overcome.

Claims 22-35 depend, directly or indirectly, from Claim 21 and, thus, are patentable for at least the same reasons that Claim 21 is patentable over the applied art. Therefore, allowance of Claims 21-35 is respectfully requested.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed
11/814,155	INTRAPARIETAL REINFORCING DEVICE FOR BIOLOGICAL CARDIAC PROSTHESIS AND REINFORCED BIOLOGICAL HEART VALVE PROSTHESIS	July 17, 2007
11/775,043	REINFORCEMENT DEVICE FOR A BIOLOGICAL VALVE AND REINFORCED BIOLOGICAL VALVE	July 9, 2007

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### **CONCLUSION**

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, early issuance of a Notice of Allowance is most earnestly solicited.

Any remarks in support of patentability of one claim should not be imputed to any other claim in this or a related application, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on solely that portion; rather, patentability must rest on each claim taken as a whole. Applicant has not presented arguments concerning whether the applied references can be properly combined in view of the clearly missing elements noted above, and Applicant reserves the right to later contest whether a proper reason exists to combine these references.

Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art discloses or teaches, even if not expressly discussed herein. Although changes to the claims have been made, no acquiescence or estoppel is or should be implied thereby; such amendments are made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter.

The undersigned has made a good faith effort to respond to all of the noted rejections and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if an issue requires clarification, the Examiner is respectfully requested to call Applicant's attorney in order to resolve any such issue promptly.


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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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